

Effective Filing Date

The effective filing date for claims 13-14 is 20 February 2002, the filing date of provisional application number 60/357,661, which teaches the down-regulation of the R1 gene for the reduction of cold-sweetening in transformed potato tubers, thus reducing the accumulation of Maillard reaction products which cause browning in fried foods. See, e.g., paragraph bridging pages 21 and 22; page 37, bottom paragraph.

The effective filing date for claims 4-8, 15-17, 45 and 47 is 06 May 2002, the filing date of provisional application number 60/377,602, which was the first application to teach the reduction of cold-sweetening for reducing acrylamide. See, e.g., page 19, bottom paragraph; page 39, middle paragraph; page 70, bottom paragraph.

The effective filing date for claims 44 and 46 is 27 June 2003, the filing date of parent application number 10/607,538, which was the first application to disclose SEQ ID NO:93.

Specification Objections

Continuity Data

Page 1 of the specification is objected to for its omission of the international application number and filing date, the patent numbers of the issued parent and grandparent applications, and the filing dates of the provisional applications. The following amendments, presented in shorthand format for brevity, would obviate this objection:

On page 1, paragraph [0001], line 1, replace the phrase "This International application claims priority to" with the following:

---This is a 371 of PCT/US2004/017424 filed 25 June 2004, which is a continuation of---

On page 1, paragraph [0001], line 2, insert ---now US Patent 7,534,934, --- after "2003,".

On page 1, paragraph [0001], line 4, insert --- now US Patent 7,250,554, --- after "2003,".

On page 1, paragraph [0001], line 5, insert ---filed February 20, 2002--- and --- filed May 6, 2002--- after the first and second provisional application numbers, respectively.

All specification amendments should comply with 37 CFR 1.121(b).

Information Disclosure Statement

In the Information Disclosure Statement of 19 October 2011, the following two references were not supplied: EP 0,853,675 and EP 1,009,842. If these references were supplied in a parent application, Applicant is requested to identify which application, and which IDS within that application, supplied them. Alternatively, Applicant may file a supplemental IDS which lists and supplies these foreign patents.

Non-Statutory Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 4, 44 and 46 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over **claims 1 and 12** of U.S. Patent No. **7,534,934**, in view of **Lorberth et al (1998 Nature Biotechnology 16: 473-477, Applicant submitted)**.

Although the conflicting claims are not identical, they are not patentably distinct from each other because *it would have been obvious to one of ordinary skill in the art to utilize the patented method of producing an Agrobacterium-transformed plant of any species by flanking a desired polynucleotide with at least one 25 nucleotide long sequence comprising SEQ ID NO:93, which sequence is not 100% identical to a T-DNA border, and which sequence facilitates integration of the desired polynucleotide into the plant genome; wherein the desired polynucleotide down-regulates at least the R1 gene; to obtain the instantly claimed tuber of a transformed plant of any species, wherein said tuber was produced by Agrobacterium-mediated transformation with a desired polynucleotide flanked by at least one 25 nucleotide long sequence comprising SEQ ID NO:93, which sequence is not 100% identical to a T-DNA border, and which sequence*

facilitates integration of the desired polynucleotide into the plant genome; wherein the desired polynucleotide comprises a sequence complementary to at least a part of the potato R1 gene, wherein the expression of the R1 gene is down-regulated in the tuber, as instantly claimed. The claims are coextensive.

The instantly claimed product would have been the obvious result of the patented claims' method, given the broad recitation of any plant species in each set of claims, so that the particular transformable plant species would have been an obvious design choice. Moreover, one of ordinary skill in the art *would have been motivated to modify the method taught by the patented claims*, to transform potato to down-regulate R1 expression in tubers thereof, to obtain the instantly claimed tubers, *in view of Lorberth et al.*

Lorberth et al teach a transformed 'Desiree' variety potato which comprises an expression cassette comprising a fragment of a potato R1 cDNA operably linked to a CaMV 35S promoter in reverse (antisense) orientation; wherein R1 gene expression was reduced, as evidenced by reduced R1 mRNA production and reduced R1 protein production. Lorberth et al teach that transformed potato tubers stored for two months at 4 degrees C exhibited a nine-fold reduction in the levels of reducing sugars, wherein said lowered levels are desirable to avoid the undesirable browning of food produced by heating cold-stored potato tubers, due to the Maillard reaction between the sugars and amino acids.

See, e.g., page 473, paragraph bridging the columns and column 2, penultimate paragraph; page 474, Figure 2; page 476, column 1, and column 2, first paragraph of "Experimental Protocol".

Thus, one of ordinary skill in the art would have been motivated to transform potato tubers to reduce R1 expression levels for their known and expected benefits.

Regarding the instantly claimed acrylamide contents of the tubers produced by the method taught by the '934 claims in view of Lorberth et al, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Claims 4, 44 and 46 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over **claim 19** of copending Application No. **12/436,389**.

Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to one of ordinary skill in the art to modify the *Agrobacterium*-mediated method of transforming a potato plant with a desired polynucleotide that alters the expression of at least two genes including the R1 gene, wherein the desired polynucleotide is flanked by at least one 25 nucleotide long sequence comprising SEQ ID NO:93, which sequence is not an *Agrobacterium* T-DNA border, and which sequence facilitates integration of the desired polynucleotide into the plant genome; to obtain a potato tuber which produces less acrylamide during the

heating required to produce food therefrom, as claimed in the copending application; *to obtain the instantly claimed* potato tuber with reduced acrylamide levels, wherein said tuber was produced by *Agrobacterium*-mediated transformation with a desired polynucleotide flanked by at least one 25 nucleotide long sequence comprising SEQ ID NO:93, which sequence is not 100% identical to a T-DNA border, and which sequence facilitates integration of the desired polynucleotide into the plant genome; wherein the desired polynucleotide comprises a sequence complementary to at least a part of the potato R1 gene, wherein the expression of the R1 gene is down-regulated (i.e. "altered") in the tuber, as instantly claimed.

It would have been obvious to one of ordinary skill in the art to down-regulate as few genes as possible, thus limiting the size of the transgene insert, for increased transformation efficiency and control. The claims are coextensive.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Improper Claim Dependency

The following is a quotation of the fourth paragraph of 35 U.S.C. 112:

Subject to the [fifth paragraph of 35 U.S.C. 112], a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.

Claim 16 is rejected under 35 U.S.C. 112, 4th paragraph, as being of improper dependent form for failing to further limit the subject matter of the claim upon which it depends, or for failing to include all the limitations of the claim upon which it depends.

Claim 16, drawn to a mature tuber, fails to further limit claim 15 on which it depends, also drawn to a mature tuber. Deletion of "mature" from claim 15 would obviate this rejection.

Applicant may cancel the claim(s), amend the claim(s) to place the claim(s) in proper dependent form, rewrite the claim(s) in independent form, or present a sufficient showing that the dependent claim(s) complies with the statutory requirements.

Anticipation

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4-8 and 13-17 are rejected under 35 U.S.C. 102(b) as being anticipated by **Kawchuck et al (US 5,998,701**, Applicant cited).

Claims 4-8 are drawn to a modified tuber including a modified potato tuber, wherein the potato tuber may be from a round or long white potato, wherein said potato exhibits lowered acrylamide levels when compared with a wild-type tuber. Claim 5 specifies that the tuber is mature, and claim 6 specifies that it is at least 12 weeks old.

Claims 13-14 are drawn to a modified tuber comprising a reduced level of cold-induced glucose, including a 40% reduction, when compared with a wild-type tuber.

Claims 15-17 are drawn to a modified tuber with a 5-fold reduction in acrylamide levels when compared to a wild-type tuber. Claim 16 specifies that the tuber is mature, and claim 17 specifies that it is at least 12 weeks old.

Kawchuk et al teach that potato tubers are routinely stored at low temperatures to inhibit disease and early sprouting, wherein said low temperature storage has the undesirable side effect of increasing the levels of reducing sugars such as fructose and glucose, wherein said elevated levels of reducing sugars result in the formation of undesirable brown pigments due to the Maillard reaction between reducing sugars and amino acids, when frying the tubers to produce food.

Kawchuk et al teach transformation of plants of the white-fleshed potato variety 'Desiree' with an expression cassette comprising fragments of the potato L-phosphorylase gene operably linked to a plant promoter in antisense orientation, wherein mature tubers from said transformed plant exhibited reduced levels of L-phosphorylase expression and reduced levels of reducing sugars after cold storage at 4 degrees C for three to six months (i.e. greater than 12 weeks), including a greater than 40% reduction in glucose content, wherein chips produced by frying pieces of said transformed tubers exhibited lighter color in comparison to chips produced from untransformed tubers. **Kawchuk et al suggest** that this method may be applied to other commercial varieties.

See, e.g., Figures 1 and 9; column 1, lines 16-42; column 3, lines 50-56 and 65-67; column 4, lines 1-43 and 65-67; column 5, lines 1-11 and 27-31; column 6, lines 8-12; column 17, lines 17-25; column 18, lines 23-45; column 19, lines 1-36; column 20, lines 31-67; column 21, lines 1-37; column 23, line 30 through column 25, line 63.

Regarding the reduced acrylamide levels of instant claims 4-8 and 15-17, these reduced acrylamide levels would have been inherent to potato tubers with reduced

glucose levels, *as evidenced by* the instant specification; and as evidenced by instant claims 45 and 47, as discussed below. It is noted that instant claims 4-8 and 15-17 are drawn to modified tubers which exhibit a particular inherent property, as opposed to being drawn to a method for measuring acrylamide content in tubers.

Claims 4-8 and 13-17 are rejected under 35 U.S.C. 102(b) as being anticipated by **Harvey et al (1998**, New Zealand Journal of Crop and Horticultural Science 26: 89-93, Applicant submitted).

Harvey et al teach the selection of potato varieties which have been produced by genetic modification (or breeding), storing tubers of said varieties from 2 to 5 months (i.e. greater than 12 weeks) at 4 degrees C, identifying those potato varieties which have consistently lowered cold storage-induced accumulation of soluble sugars including the reducing sugar glucose, utilizing said selected potato varieties for producing chips ("crisps") via frying at high temperatures, wherein said selected potato varieties produced chips with lowered levels of undesirable Maillard reaction products, as evidenced by their lighter color, wherein the Maillard reaction involves reducing sugars and amino acids. Harvey et al teach that sugar accumulation was highly genetically influenced.

Harvey et al also teach the "reconditioning" treatment of cold-stored potato tubers in order to lower sugar accumulation, said treatment comprising the incubation of previously cold-stored tubers at 18-20 degrees C, wherein said reconditioning resulted in reduced accumulation of reducing sugars or soluble sugars such as glucose; and

wherein said reconditioned tubers produced fried food with lowered levels of Maillard reaction products. Said reconditioning constitutes tuber modification as claimed.

See, e.g., page 89, Abstract; paragraph bridging pages 89 and 90; page 90; page 91, paragraph bridging the columns and column 2, first through third full paragraphs; paragraph bridging pages 91 and 92; page 92.

The claimed reduced acrylamide levels would have been an inherent property of the tubers taught by Harvey et al which have reduced glucose and reduced Maillard reaction products, as discussed above.

Claims 4-5, 7-8, 13-16, 45 and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by **Lorberth et al (1998, Nature Biotechnology 16: 473-477, Applicant submitted)**.

Claims 45 and 47 are drawn to tubers with reduced levels of acrylamide and cold-induced glucose, respectively, which tubers also have downregulated R1 gene expression.

Lorberth et al teach a transformed white-fleshed 'Desiree' variety potato which comprises an expression cassette comprising a fragment of a potato R1 cDNA operably linked to a CaMV 35S promoter in reverse (antisense) orientation; wherein R1 gene expression was reduced in tubers, as evidenced by reduced R1 mRNA production and reduced R1 protein production. **Lorberth et al teach** the comparison of tuber yield between transformed and wild-type tubers, indicating that mature tubers were assayed. **Lorberth et al teach** that transformed potato tubers stored for two months at 4 degrees C exhibited a nine-fold reduction in the levels of reducing sugars, including at least a

five-fold reduction in cold-induced glucose levels; wherein said lowered levels are desirable to avoid the undesirable browning of food produced by heating cold-stored potato tubers, due to the Maillard reaction between the sugars and amino acids.

See, e.g., page 473, paragraph bridging the columns and column 2, penultimate paragraph; paragraph bridging pages 473 and 474; page 474, Figure 2; page 476, column 1, and column 2, first paragraph of "Experimental Protocol".

The potato tubers taught by Lorberth et al, exhibiting down-regulated R1 gene expression and lowered glucose levels, would *inherently exhibit* a lowered acrylamide content; *given the dependency of claim 45 on claim 4*. These claims indicate that the only requirement for reduced acrylamide levels is a reduction in R1 expression, which inherently reduces cold-induced glucose content as taught by Lorberth et al.

Obviousness

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4-8 and 13-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Kawchuk et al (US 5,998,701)** in view of **Tareke et al (2000, Chemical Research in Toxicology 13: 517-522, Applicant submitted)**.

For the purpose of this rejection, the claims are interpreted as being drawn to transformed Russet potatoes whose exact acrylamide content is determined.

Kawchuk et al teach a method of producing mature potato tubers with lowered levels of cold-induced glucose accumulation, wherein said lowered glucose levels resulted in fried food products with reduced Maillard reaction products and thus exhibited desirable light color, as discussed above.

Kawchuk et al suggest the application of their process to "commercial processing potato varieties" (see, e.g., column 21, lines 30-37).

Kawchuk et al do not teach the transformation of Russet potatoes or measurement of acrylamide levels therein.

Tareke et al (2000) teach that acrylamide is an undesirable Maillard reaction product, wherein fried food which exhibits a dark brown color contains higher acrylamide levels, wherein acrylamide levels have been correlated with neural damage and tumor incidence in humans. See, e.g., page 517, column 1, first full paragraph of the Introduction; page 518, column 2, penultimate paragraph; page 519, column 1, penultimate paragraph; page 520, column 1, bottom two paragraphs and column 2, top two paragraphs; page 521, column 1, bottom two paragraphs.

It would have been obvious to one of ordinary skill in the art to utilize the method for making potatoes with reduced sugar levels and therefore reduced Maillard reaction product levels after frying, as taught by Kawchuk et al; and to modify that method by incorporating commercial processing potato varieties as suggested by Kawchuk, including the known Russet variety. It would have been further obvious to measure acrylamide levels in the fried foods, and selecting those potatoes which produced fried foods with the lowest acrylamide levels, in order to minimize adverse effects on human health, as suggested by Tareke et al (2000). Choice of cold storage duration would have been the optimization of process parameters.

Claims 4-8 and 13-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Harvey et al (1998**, New Zealand Journal of Crop and Horticultural Science 26: 89-93) in view of **Tareke et al (2000**, Chemical Research in Toxicology 13: 517-522, Applicant submitted).

For the purpose of this rejection, the claims are interpreted as being drawn to transformed Russet potatoes whose exact acrylamide content is determined.

Harvey et al teach a method of producing potato tubers with lowered levels of cold-induced glucose accumulation, wherein said lowered glucose levels resulted in fried food products with reduced Maillard reaction products and thus exhibited desirable light color, as discussed above.

Harvey et al teach that lowering cold-induced sweetening in a variety of commercial or locally-adapted cultivars is desirable, and that the search for potato varieties with lowered cold-induced sweetening is being applied to a variety of

commercial or locally-adapted cultivars (see, e.g., page 90, column 1, first full paragraph).

Harvey et al do not teach the transformation of Russet potatoes or measurement of acrylamide levels therein.

Tareke et al (2000) teach that acrylamide is an undesirable Maillard reaction product, wherein fried food which exhibits a dark brown color contains higher acrylamide levels, wherein acrylamide levels have been correlated with neural damage and tumor incidence in humans; as discussed above.

It would have been obvious to one of ordinary skill in the art to utilize the method for making potatoes with reduced sugar levels and therefore reduced Maillard reaction product levels after frying, as taught by Harvey et al; and to modify that method by incorporating known commercial potato varieties as suggested by Harvey et al, including the known Russet variety. It would have been further obvious to measure acrylamide levels in the fried foods, and selecting those potatoes which produced fried foods with the lowest acrylamide levels, in order to minimize adverse effects on human health, as suggested by Tareke et al (2000). The use of mature tubers would have been obvious, since tubers of this stage are utilized in food processing. Choice of cold storage duration would have been the optimization of process parameters.

Claims 4-8, 13-17, 45 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Lorberth et al** (1998, Nature Biotechnology 16: 473-477) in view of **Tareke et al (2000, Chemical Research in Toxicology 13: 517-522).**

For the purpose of this rejection, the claims are interpreted as being drawn to transformed Russet potatoes whose exact acrylamide content is determined.

Lorberth et al teach a method of producing potato tubers with lowered levels of R1 protein and cold-induced glucose accumulation, wherein said lowered glucose levels will result in fried food products with reduced Maillard reaction products and thus exhibited desirable light color, as discussed above.

Lorberth et al teach that lowering cold-induced sweetening would be desirable “for the potato processing industry” (see, e.g., page 476, column 1, penultimate paragraph).

Lorberth et al do not teach the transformation of Russet potatoes or measurement of acrylamide levels therein.

Tareke et al (2000) teach that acrylamide is an undesirable Maillard reaction product, wherein fried food which exhibits a dark brown color contains higher acrylamide levels, wherein acrylamide levels have been correlated with neural damage and tumor incidence in humans; as discussed above.

It would have been obvious to one of ordinary skill in the art to utilize the method for making potatoes with reduced R1 protein levels and sugar levels and therefore reduced Maillard reaction product levels after frying, as taught by Lorberth et al; and to modify that method by incorporating known commercial potato varieties as suggested by Lorberth et al, including the known Russet variety. It would have been further obvious to measure acrylamide levels in the fried foods, and selecting those potatoes which produced fried foods with the lowest acrylamide levels, in order to

minimize adverse effects on human health, as suggested by Tareke et al (2000). The use of mature tubers would have been obvious, since tubers of this stage are utilized in food processing. Choice of cold storage duration would have been the optimization of process parameters.

Conclusion

Claims 44 and 46 are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest the use of an isolated, non-*Agrobacterium*-derived 25 nucleotide-long sequence comprising SEQ ID NO:93 to flank a desired polynucleotide; for integration of said desired polynucleotide into a plant genome by *Agrobacterium*-mediated transformation; as stated in parent application 10/607,538, now US Patent 7,534,934.

No claim is allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (571) 272-0795. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/DAVID T FOX/
Primary Examiner, Art Unit 1638

November 4, 2011